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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/973,850 | 10/10/2001 | Richard Glenn Wunderink | GCI-0017 | 7130 |

7590 05/23/2003

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66 E. Main Street
Marlton, NJ 08053

| EXAMINER |
|---|
| HASHEMI, SHAR S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/973,850 | Applicant(s) WUNDERINK ET AL. | |
|---|---|---|---|
| | Examiner Shar Hashemi | Art Unit 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *"Notice to Comply"* .

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The claims pending in this application are **Claim(s) 1-5.**

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on 01/17/03 was entered as Paper No. 5. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Sequence Rules*

3. This application does not comply with the sequence rules for the reasons set forth below.

This application contains sequence disclosures (see claims 1-3 and 5) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequence disclosures must have SEQ ID NO identifiers. Moreover, the TNFalpha gene recited on page 15 must be labeled with SEQ ID NO identifiers.

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing petition accompanied by

the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response. The application is not in compliance for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report

***Election/Restrictions***

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method of identifying a patient at an increased risk of death from community-acquired pneumonia, classified in class 435, subclass 6.

II. Claim 2, drawn to a method of treating patients with a pneumococcal and/or influenza vaccine, classified in class 435, subclass 235.1.

III. Claims 3-4, drawn to an agonist and methods of screening to identify compounds which stimulate the action or synthesis of the TNFalpha polypeptide, classified in class 435, subclass 69.1.

IV. Claims 3-4, drawn to an antagonists and methods of screening to identify compounds which inhibit the action or synthesis of the TNFalpha polypeptide, classified in class 435, subclass 69.1.

V. Claims 23-25, drawn to a method of treating community-acquired pneumonia by administering an antagonist, classified in class 435, subclass 7.1.

5. The inventions are distinct, each from the other because of the following reasons:

Restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, II, III, IV and V are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires the search of methods for identifying a patient at an increased risk of death from community-acquired pneumonia, which is not required by groups II, III, IV and V. Invention II requires the search of methods of treating patients with a pneumococcal and/or influenza vaccine, which is not required by groups I, III, IV and V. Invention III requires the search of agonists and methods of screening to identify compounds which stimulate the action or synthesis of the TNFalpha polypeptide, which is not required by groups I, II, IV and V. Invention IV requires the search of antagonists and methods of screening to identify compounds which inhibit the action or synthesis of the TNFalpha polypeptide, which is not required by groups I, II, III and V. Invention V requires the search of methods for treating community-acquired pneumonia by administering an antagonist, which is not required by groups I, II, III, and IV. Therefore, a search and examination of all five methods in one patent application would result in an undue burden, since the searches for the five methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

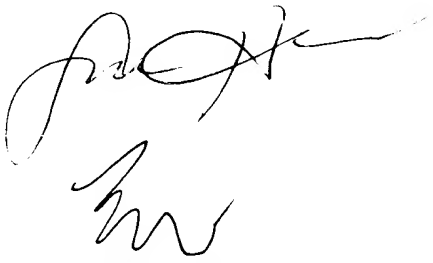
## CONCLUSION

6. Claims 1-5 are restricted for the reasons set forth above.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:30AM – 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, the examiner's supervisor, Gary Benzion, Ph.D., can be reached on (703) 308-1119.

The fax number for this Examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tracey Johnson whose telephone number is (703) 305-2982.

Examiner Hashemi



Ethan Whisenant, Ph.D
Primary Examiner
Art Unit 1634

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| APPLICATION NUMBER | FILING/RECEIPT DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 09/973,850 | 10/10/01 | Richard Glenn Wunderink | GC1-0017 |

DATE MAILED:

## NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821–1.825 for the following reason(s):

☑ 1. This application fails to comply with the requirements of 37 CFR 1.821–1.825.

☑ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☑ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked–up copy of the "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☑ 7. OTHER: nucleotide and/or amino acid sequences must be labeled with SEQ ID NO "identifiers"

APPLICANT MUST PROVIDE:

☑ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing."

☑ An initial or substitute paper copy of the "Sequence Listing," as well as an amendment directing its entry into the specification.

☑ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE CONTACT:

☑ For Rules Interpretation, call (703) 308–1123.

☑ For CRF submission help, call (703) 308–4212.

☑ For PatentIn software help, call (703) 308–6856.

Customer Service Center
Initial Patent Examination Division (703) 308–1202

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